Claim 24 is rejected under 35 USC 103(a) as being unpatentable over Chatterjee [US Pat no. 5,688,731] in view of Tziviskos [US Pat no. 6,011,993], further in view of Whitehurst [US Pat no. 6,735,475] and Tsukuma [US Pat no. 4,587,225].

CLAIMS

The claims are resubmitted without amendment to facilitate their review.

DISCUSSION

Claims 1-3 and 5-18 are rejected under 35 USC 103(a) as being unpatentable over Chatterjee [US Pat no. 5,688,731] in view of Tziviskos [US Pat no. 6,011,993].

Claims 1-3

Applicants teach, "...that hot isostatic pressing a sintered yttria-stabilized tetragonal zirconia polycrystalline ceramic (Y-TZP) dramatically reduces the destructive phase transformation from tetragonal to monoclinic." [emphasis added] [Application, Detailed Description of the Preferred Embodiment, page 4, first paragraph]

No discussion is presented in the Office action with respect to Applicants' claim 5, so this claim is presumed to be allowable over Chatterjee and Tziviskos.

In view of the dramatic difference between Applicants' teaching of a post-sinter [i.e., a post-densification hot isostatic pressing] of the ceramic component, independent claims 1 and 10 are allowable over Chatterjee in view of Tziviskos as will be discussed. Chatterjee teaches hot isostatic pressing the prime method of densification in lieu of sintering. The Examiner correctly characterizes Applicants' invention at page 3, first paragraph, second sentence, saying, "The process for creating the material involves a sequence of sintering and compacting happening consecutively...." However, the second half of the sentence quotes Chatterjee, as, "...though the order in which one occurs is not critical, col 5 lines 50-58, wherein the compacting step is hot isostatic pressing." This is true for Chatterjee, where he merely wants to densify the ceramic for electrical conductivity

optimization, wear and abrasion resistance. [col 3, lines 29-33] These are not relevant properties to Applicants' invention, which is implantable and which eliminates low-temperature degradation of the sintered implantable case. In contrast, Applicants teach that the starting [near net shape] body is already densified by sintering before it is treated by hot isostatic pressing. Then the Examiner further confuses the definition of "compacting" as taught by Chatterjee. Chatterjee first compacts, such as by cold pressing [col 6, lines 8-25], then densifies by sintering or hot isostatic pressing, the order of sintering or hot isostatic pressing not being critical.

Applicants teach that the component is fully sintered to its final size and shape first. Then the component is hot isostatically pressed to result in a component that retains the size and shape that resulted from sintering but that is also now resistant to the destructive phase changes which would destroy the sintered component absent the hot isostatic pressing treatment.

Chatterjee teaches a process for forming composites of boron, phosphorus, and alumina that contain Y-TZP primarily involving mixing and ball milling, pressing is a die and sintering in an argon atmosphere between 1300 and 1700 C. [col 3, lines 26-30] Further, Chatterjee teaches that these alloys or composite ceramics are compacted and sintered in argon to achieve a tetragonal zirconia and zirconium diboride. [col 3, lines 61-67] Chatterjee casually mentions that these zirconia alloys or zirconia alumina composites and zirconium diboride is compacted and heated to sinter in argon gas. He teaches that the "...compaction and sintering can be simultaneous in a single operation or partial compaction can be followed by sintering and further compaction utilizing a process like hot isostatic pressing (HIP)." [col 5, lines 53-54] Chatterjee continues to clarify,

> "The interim product of compacting and sintering operations or fully sintered product is referred to herein as a "blank", which is illustrated as element 110 in FIG. 1. Blank 110 is at least partially compacted and is either unsintered or not fully sintered or alternatively is fully sintered or hot isostatically pressed.
>
> Completion of compacting and sintering provides the finished ceramic or ceramic composite articles 110, which have high sintered densities (at least greater than 90% of the theoretical) ..." [col 5, lines 58-67]

Again Chatterjee teaches, "These composites can be hot isostatically pressed to achieve near 100% of theoretical density and improve the fracture toughness without degrading the electrical conductivity...." [col 7, lines 52-58]

Chatterjee uses hot isostatic pressing to complete densification of a partially densified product, in dramatic contrast with the post-densification teachings of Applicants.

Applicants have found that controlling the post-sintering hot isostatic pressing not only allows the near-net shape of the sintered ceramic to be preserved, but the average grain size can be <u>maintained</u> at less than 0.5 microns, as claimed in claim 1. Applicants do not teach a "blank" as taught by Chatterjee, but rather claim the ceramic as an implantable hollow tube, which is only achievable if the component is densified prior to hot isostatic pressing.

The Office action [page 3] points to Chatterjee at col 6 lines 8-25, for example, as teaching compaction by hot isostatic pressing, but Chaterjee is NOT teaching "hot isostatic pressing" [Office action at page 3 middle of the page]. Instead, Chatterjee teaches cold pressing or "compaction" at col 6, lines 8-25. Again, Chatterjee teaches sintering only at col 6 lines 26-43 and does not not hot isostatic pressing, as presented in the Office action. [Office action, page 3, middle of the page]

Combining Chatterjee with Tziviskos does not overcome these deficiencies so as to render claim 1 obvious. In addition to the deficiencies discussed above, Chatterjee does not teach the use of the ceramic as an implantable medical device housing. The devices taught by Chatterjee, which contain dominant amounts of diboride are not known or presented to be implantable materials.

Tziviskos does not teach that the diboride taught by Chatterjee is implantable. Tziviskos teaches a material that is similar in composition to that claimed by Applicants, but which is not taught by Chatterjee.

Combining Chatterjee with Tziviskos does not render claim 1 obvious. Claims 2 and 3 as well as claims 5-9 are allowable as further limitations on an allowable independent claim 1.

Claim 10

Addressing independent claim 10 next, this Jepson-type claim teaches a method of producing an improved long-lived, implantable case comprised of stabilized tetragonal zirconia polycrystal ceramic. The improvement is hot isostatic pressing of the implantable case to eliminate low-temperature degradation of the case. One starts with a sintered [i.e., densified] ceramic case and post-sintering applied hot isostatic pressing. [see Application at page 4, paragraph 1]

No discussion is presented in the Office action with respect to Applicants' claims 13 and 14, so these claims are presumed to be allowable over Chatterjee and Tziviskos.

As discussed above, Chatterjee does not render claim 10 obvious since he teaches a different material that is prepared by compaction followed by a densification step "the order in which one occurs is not critical."

Combining Chatterjee with Tziviskos does not render claim 10 obvious for the same reasons as discussed above. Therefore Claim 10 is allowable and dependent claims 11-18 are allowable as further limitations on allowable claim 10.

The Examiner argues [Office action page 4] that dependent claims 11 and 12 are obvious because Chatterjee teaches a 3 mole percent yttria addition yielding tetragonal zirconium oxide [at col 5, lines 23-24 and col 4 lines 9-42]. A close reading of Chatterjee at the cited col 5 lines 23-24 indicates that Chatterjee is mixing zirconium diboride with zirconia alloy in a ball mill. The yttria containing yttria is merely an admixture to the diboride material to yield a diboride-rich product. This is not a similar material to that taught by Applicants for implantation.

The Examiner argues [Office action page 4] that dependent claims 6 and 15 are rendered obvious by Chatterjee's teaching of "the sintering process of Chatterjee" at a controlled temperature between 1300 to 1600C, col 6 lines 36-37. However, Applicants' claims 6 and 15 are limitation to the step of hot isostatic pressing and not to sintering, hence Chatterjee cannot render claims 6 and 15 obvious.

The Examiner argues [Office action page 4] that claims 7 and 16 are obvious because Chatterjee teaches hot isostatic pressing at a pressure between

69 and 207 MPa citing col 6 lines 8-25. However, Chatterjee teaches cold conventional compaction of a powder mixture in preparation for densification at col 6 lines 8-25 and not hot isostatic pressing. Chatterjee does not render claims 7 and 16 obvious with this teaching of cold compaction.

Claims 5, 14, 19-23, and 25-28 are rejected under 35 USC 103(a) as being unpatentable over Chatterjee [US Pat no. 5,688,731 in view of Tziviskos [US Pat no. 6,011,993], further in view of Whitehurst [US Pat no. 6,735,475].

The Examiner admits that claims 5, 14, 19-23, and 25-28 are not rendered obvious by Chatterjee in view of Tziviskos absent Whitehurst. With respect to independent claims 19 and 23, The above arguments are incorporated here and are not repeated that the claimed device is patentably distinct over the prior art of Chatterjee and Tziviskos. Claims 19 and 23 are therefore allowable as presented.

The Examiner admits that the limitation to dimensions of the implantable housing are not taught by Chatterjee or Tziviskos and argues that Whitehurst cures this deficiency. However, this argument is rendered moot since the combination of Chatterjee with Tziviskos fail to render claims 19 and 23 obvious and Whitehurst does not address the previously presented deficiencies.

Dependent claims 5, 14, 22, 27, and 28 are allowable as further limitations on allowable independent claims.

Dependent claims 20 and 26 teach a limitation to hot isostatic pressing, however the Examiner [Office action, page 6] cites Chatterjee at col 6 lines 8-25 as teaching hot isostatic pressing. However, as discussed previously, Chatterjee teaches cold compaction of a powder compact at col 6 lines 8-25. These claims 20 and 26 are therefore allowable.

Dependent claims 21 and 25, which teach hot isostatic pressing as a limitation, are objected to by the Examiner. [Office action, page 6] However, Chatterjee teaches sintering at col 6 lines 36-37 and not hot isostatic pressing. This objection is moot and the claims 21 and 25 are allowable.

Claim 24 is rejected under 35 USC 103(a) as being unpatentable over Chatterjee [US Pat no. 5,688,731] in view of Tziviskos [US Pat no. 6,011,993], further in view of Whitehurst [US Pat no. 6,735,475] and Tsukuma [US Pat no. 4,587,225].

Dependent method claim 24 is allowable as a further limitation on allowable claim 23. As discussed above, Chatterjee in combination with Tziviskos and Whitehurst do not anticipate the invention as claimed by Applicants. Tsukuma bends a conventional "...test piece having a width of 4 mm, a thickness of 3 mm and a length of 40 mm is broken when it is bent at a span length of 30 mm and a crosshead speed of 0.5 mm/min." [Col 3, lines 32-35] Applicants load the implantable case itself, which has a length outside diameter, and a wall thickness. Tsukuma does not teach this novel approach and therefore does not render the claim obvious.

In view of the foregoing, it is respectfully submitted that the pending claims 1-3 and 5-28 are allowable. Reexamination and allowance are respectfully requested.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case. If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is requested to call the undersigned attorney at the Los Angeles, California area telephone number (661) 702-6814 to discuss the steps necessary for placing the application in condition for allowance.

Respectfully submitted,

10/22/2008

Date

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